

REMARKS

An Information Disclosure Statement accompanies this amendment. The Statement seeks cross-citation of documents cited in co-pending Applications Serial Nos. 09/389,497, filed September 3, 1999, entitled "Blood Processing Systems and Methods with On-Line Mixing of Replacement Fluids" (currently pending before Examiner P. Bianco, Art Group 3762), 09/390,268, filed September 3, 1999, entitled "Programmable Fluid Pressure Actuated Blood Processing Systems and Methods" (currently pending before Examiner L. Deak, Art Group 3762), and 09/390,265, filed September 3, 1999, entitled "Fluid Pressure Actuated Blood Pumping Systems and Methods with Continuous Inflow and Pulsatile Outflow Conditions" (currently pending before Examiner L. Deak, Art Group 3762), all of which are owned by the assignee of the instant application.

Claims 1-3, 6-19, 22-34, 36-40 and 43-46 remain in the application. Of these, claims 1, 7, 19, 23 and 28 are independent apparatus claims and claims 29 and 40 are independent method claims.

The Examiner indicates that claims 5-8, 21-24, 28, 35-39 and 42-46 would be allowable if rewritten in independent form. The claims have been amended in light of this indication of allowability as follows:

- (1). Claims 4, 5, 20, 21, 35, 41 and 42 have been canceled.
- (2). Claim 1 has been amended to incorporate the subject matter of claims 1, 4 and 5 as filed.
- (3). Claim 7 has been amended to incorporate the subject matter of claims 1 and 7 as filed, and additionally to claim that processing fluid is conveyed into the blood processing flow channel or the blood component flow channel for mixing with the blood component. Support for this subject matter is found, e.g., on Specification page 115, lines 5-10.
- (4). Claims 2, 9, 10, 12, 14 and 16-18 have been amended to depend on amended claims 1 or 7.
- (5). Claim 6 has been amended to depend on amended claim 1.
- (6). Claim 19 has been amended to incorporate the subject matter of claims 19, 20 and 21 as filed.
- (7). Claim 22 has been amended to depend on amended claim 19.
- (8). Claim 23 has been amended to incorporate the subject matter of claims 19 and 23 as filed, and additionally to claim that processing fluid is conveyed into the blood processing flow channel or the blood component flow channel for mixing with the blood component. Support for this subject matter is found, e.g., on Specification page 115, lines 5-10.

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(9). Claim 28 has been amended to incorporate the subject matter of claims 19 and 28 as filed.

(10). Claim 29 has been amended to incorporate the subject matter of claims 29 and 35 as filed, and additionally to claim that processing fluid is conveyed into the blood processing flow channel or the blood component flow channel for mixing with the blood component. Support for this subject matter is found, e.g., on Specification page 115, lines 5-10.

(11). Claim 33 has been amended to reflect amendments made to independent claim 29, from which claim 33 depends.

(12). Claim 36 has been amended to depend on amended claim 29.

(13). Claim 40 has been amended to incorporate the subject matter of claims 40, 41 and 42.

(14). Claim 43 has been amended to depend on amended claim 40.

(15). Claim 44 has been amended to claim that processing fluid is conveyed into the blood processing flow channel or the blood component flow channel for mixing with the blood component. Support for this subject matter is found, e.g., on Specification page 115, lines 5-10.

In compliance with 37 C.F.R. §121(c)(3), a clean version of the entire set of pending claims is being submitted, as is a marked-up version showing changes in the amended claims 1, 2, 6, 7, 9, 10, 12, 14, 16-19, 22, 23, 28, 29, 33, 36, 40, 43 and 44 relative to the previous version of the claims.

Applicant believes the foregoing amendments place the case in condition for allowance. Allowance of claims 1-3, 6-19, 22-34, 36-40 and 43-46 is respectfully requested.

Respectfully submitted,

By


Daniel D. Ryan
Registration No. 29,243

RYAN KROMHOLZ & MANION, S.C.
P.O. Box 26618
Milwaukee, Wisconsin 53226-0618
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389504a.ddy

Marked-Up Version of Amended Claims

1, 2, 6, 7, 9, 10, 12, 14, 16-19, 22, 23, 28, 29, 33, 36, 40, 43 and 44

1 (Once amended). A blood processing system comprising
a donor flow channel to convey fluid to and from a donor,
a blood processing flow channel including a blood separation chamber to separate a
blood component from donor blood,
a blood component collection flow channel including a blood component collection
container,
a pump station communicating with the donor flow channel, the blood processing flow
channel, and the blood component collection flow channel, [and]
a controller to operate the pump station in multiple modes, including a processing mode,
during which the pump station is operated to convey blood in the donor flow channel into the blood
processing flow channel for separation of the blood component in the blood separation chamber,
and a collection mode, during which the pump station is operated to convey at least some of the
blood component in the blood processing flow channel into the blood component collection flow
channel for collection in the blood component collection container, and a blood component return
mode, during which the pump station is operated to convey at least some of the blood component in
the blood processing flow channel into the donor flow channel for return to the donor, and
a utility flow channel including a processing fluid container,
the pump station communicating with the utility flow channel, and
the controller configured to operate the pump station during the blood component return
mode to convey processing fluid in the utility flow channel into the donor flow channel for mixing with
the blood component returned to the donor.

2 (Once amended). A system according to claim 1 or 7
wherein the blood component collection flow channel includes a filter to remove
undesired materials from the blood component before entering the blood component collection
container.

6 (Once amended). A system according to claim [5] 1
wherein the processing fluid includes saline.

7 (Once amended). [A system according to claim 1] A blood processing system
comprising
a donor flow channel to convey fluid to and from a donor,
a blood processing flow channel including a blood separation chamber to separate a

blood component from donor blood,

a blood component collection flow channel including a blood component collection container,

a pump station communicating with the donor flow channel, the blood processing flow channel, and the blood component collection flow channel,

a controller to operate the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey blood in the donor flow channel into the blood processing flow channel for separation of the blood component in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the blood component in the blood processing flow channel into the blood component collection flow channel for collection in the blood component collection container, and

[further including] a utility flow channel including a processing fluid container,

[wherein] the pump station [communicates] communicating with the utility flow channel,

and

[wherein] the controller configured to operate[s] the pump station in a processing fluid transfer mode, during which the pump station is operated to convey processing fluid in the utility flow channel into the blood processing flow channel or the blood component collection flow channel for mixing with the blood component.

9 (Once amended). A system according to claim 1 or 7

wherein the pump station includes a fluid pressure actuated pump and an actuator to apply fluid pressure to the pump, and

wherein the controller is coupled to the actuator.

10 (Once amended). A system according to claim 1 or 7

wherein the pump station, the donor flow channel, the blood processing flow channel, and the blood component collection flow channel communicate within a cassette.

12 (Once amended). A system according to claim 1 or 7

wherein the blood processing flow channel includes a blood component holding container to hold the blood component, and

wherein, in the collection mode, the pump station is operated to convey at least some of the blood component in the blood component holding container into the blood component collection flow channel.

14 (Once amended). A system according to claim 1 or 7

wherein the blood processing flow channel includes a donor blood holding container to

hold donor blood prior to separation in the blood separation chamber, and

wherein, in the processing mode, the pump station is operated to convey blood in the donor flow channel into the donor blood holding container.

16 (Once amended). A system according to claim 1 or 7

wherein the pump station comprises first and second fluid pressure actuated pump stations, and a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to the first and second pump stations to convey fluid from a source to a destination,

wherein, during at least one of the multiple modes, the controller switches between a first flow state, in which the pump strokes draw a fluid volume into the first pump station from the source and expel a fluid volume from the second pump station to the destination, and a second flow state, in which the pump strokes draw a fluid volume into the second pump station from the source and expel a fluid volume from the first pump station to the destination, the control function operating to synchronize the pump strokes so that fluid flow from the source is essentially continuous while fluid flow to the destination is pulsatile.

17 (Once amended). A system according to claim 1 or 7

wherein the blood component comprises red blood cells.

18 (Once amended). A system according to claim 1 or 7

wherein the blood component comprises plasma.

19 (Once amended). A blood processing system comprising

a donor flow channel to convey fluid to and from a donor,

a blood processing flow channel including a blood separation chamber to separate red blood cells from donor whole blood,

a blood component collection flow channel including a red blood cell collection container and an in-line filter to remove leukocytes from the red blood cells before entering the red blood cell collection container,

a pump station communicating with the donor flow channel, the blood processing flow channel, and the blood component collection flow channel, [and]

a controller to operate the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey whole blood in the donor flow channel into the blood processing flow channel for separation of the red blood cells in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the blood component collection flow channel for on-line removal of leukocytes and collection in the red blood cell collection container, and a

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blood component return mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the donor flow channel for return to the donor, and

a utility flow channel including a processing fluid container,
the pump station communicating with the utility flow channel, and
the controller configured to operate the pump station during the blood component return mode to convey processing fluid in the utility flow channel into the donor flow channel for mixing with the red blood cells returned to the donor.

22 (Once amended). A system according to claim [21] 19
wherein the processing fluid includes saline.

23 (Once amended). [A system according to claim 19] A blood processing system comprising

a donor flow channel to convey fluid to and from a donor,
a blood processing flow channel including a blood separation chamber to separate red blood cells from donor whole blood,

a blood component collection flow channel including a red blood cell collection container and an in-line filter to remove leukocytes from the red blood cells before entering the red blood cell collection container,

a pump station communicating with the donor flow channel, the blood processing flow channel, and the blood component collection flow channel,

a controller to operate the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey whole blood in the donor flow channel into the blood processing flow channel for separation of the red blood cells in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the blood component collection flow channel for on-line removal of leukocytes and collection in the red blood cell collection container, and

[further including] a utility flow channel including a processing fluid container,
[wherein] the pump station [communicates] communicating with the utility flow channel,

and

[wherein] the controller configured to operate[s] the pump station in a processing fluid transfer mode, during which the pump station is operated to convey processing fluid in the utility flow channel into the blood processing flow channel or the blood component collection flow channel for mixing with the red blood cells.

28 (Once amended). [A system according to claim 19] A blood processing system comprising

a donor flow channel to convey fluid to and from a donor,

a blood processing flow channel including a blood separation chamber to separate red blood cells from donor whole blood,

a blood component collection flow channel including a red blood cell collection container and an in-line filter to remove leukocytes from the red blood cells before entering the red blood cell collection container,

a pump station communicating with the donor flow channel, the blood processing flow channel, and the blood component collection flow channel, and

a controller to operate the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey whole blood in the donor flow channel into the blood processing flow channel for separation of the red blood cells in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the blood component collection flow channel for on-line removal of leukocytes and collection in the red blood cell collection container,

[wherein] the pump station [comprises] comprising first and second fluid pressure actuated pump stations, and a fluid pressure actuator operating to selectively apply fluid pressure pump strokes in tandem to the first and second pump stations to convey fluid from a source to a destination,

wherein, during at least one of the multiple modes, the controller switches between a first flow state, in which the pump strokes draw a fluid volume into the first pump station from the source and expel a fluid volume from the second pump station to the destination, and a second flow state, in which the pump strokes draw a fluid volume into the second pump station from the source and expel a fluid volume from the first pump station to the destination, the control function operating to synchronize the pump strokes so that fluid flow from the source is essentially continuous while fluid flow to the destination is pulsatile.

29 (Once amended). A blood processing method comprising the steps of
coupling a multi-function pump station to a donor flow channel to convey fluid to and from a donor, a blood processing flow channel including a blood separation chamber to separate a blood component from donor blood, and a blood component collection flow channel including a blood component collection container, [and]

operating the pump station in multiple modes, including a processing mode, during

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which the pump station is operated to convey blood in the donor flow channel into the blood processing flow channel for separation of the blood component in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the blood component in the blood processing flow channel into the blood component collection flow channel for collection in the blood component collection container,

coupling the pump station to a utility flow channel including a processing fluid container,
and

operating the pump station in a processing fluid transfer mode, during which the pump station is operated to convey a processing fluid in the utility flow channel into the blood processing flow channel or the blood component collection flow channel for mixing with the blood component.

33 (Once amended). A method according to claim 29

further including [coupling the pump station to a utility flow channel including a processing fluid container,] operating the pump station during the blood component return mode to convey a processing fluid in the utility flow channel into the donor flow channel for mixing with the blood component returned to the donor.

36 (Once amended). A method according to claim [35] 29

wherein the processing fluid includes a blood component additive.

40 (Once amended). A red blood cell processing method comprising the steps of coupling a multi-function pump station to a donor flow channel to convey fluid to and from a donor, a blood processing flow channel including a blood separation chamber to separate red blood cells from donor whole blood, and a blood component collection flow channel including a red blood cell collection container and an in-line filter to remove leukocytes from the red blood cells before entering the red blood cell collection container,

operating the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey whole blood in the donor flow channel into the blood processing flow channel for separation of the red blood cells in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the blood component collection flow channel for on-line removal of leukocytes and collection in the red blood cell collection container, and a blood component return mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the donor flow channel for return to the donor,

coupling the pump station to utility flow channel including a processing fluid container,

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and

operating the pump station during the blood component return mode to convey a processing fluid in the utility flow channel into the donor flow channel for mixing with the red blood cells returned to the donor.

43 (Once amended). A method according to claim [42] 40
wherein the processing fluid includes saline.

44 (Once amended). A method according to claim 40
further including [coupling the pump station to a utility flow channel including a processing fluid container, and] operating the pump station in a processing fluid transfer mode, during which the pump station is operated to convey a processing fluid in the utility flow channel into the blood processing flow channel or the blood component collection flow channel for mixing with the red blood cells.